Poland’s ‘Medical Fund Act’: Progress of the New ‘Fast-Track’ TLI Reimbursement Pathway

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Objectives

Poland’s fast-track reimbursement mechanism for therapies used in rare diseases and/or oncology, which involves the annual publication of a list of therapies classified as “high-level pharmaceutical technology innovation" (*technologia lekowa o wysokim poziomie innowacyjnosci,* TLI), was introduced with the Medical Fund Act of November 2020. Since then, it has provided a new, accelerated pathway to reimbursement in Poland for new orphan-designated and/or oncology therapies centrally approved in the EU, within a system of coverage with evidence development. This analysis seeks to evaluate the impact of this new mechanism on the expansion of access to new medicines in Poland, as well as its impact on delays to reimbursement.

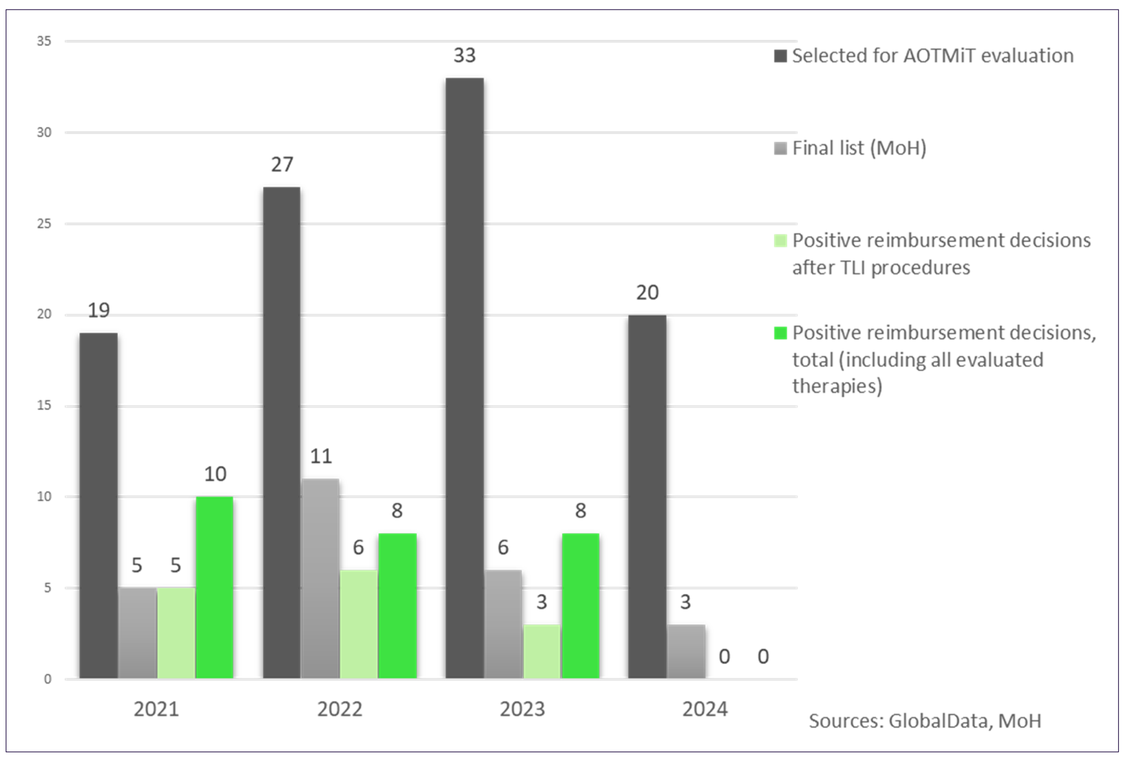
Methods

The number of therapies chosen by the Agency for Health Technology Assessment and Tariff System (AOTMiT) to be evaluated for inclusion in each TLI list was compared with the number chosen for the final Ministry of Health (MoH) list, and the number that have gained reimbursement. This was set in the context of the overall growth in centrally approved medicines gaining reimbursement. The average time to reimbursement of therapies that underwent TLI procedures ending with a positive decision was compared with the average time to the first reimbursement decisions for all on-patent medicines receiving their first centralized approvals from the beginning of 2020 – the starting point of the first TLI horizon-scanning procedure – and to the average time to the first reimbursement decisions for all on-patent therapies that have received their first centralized approval since 2010.

Results

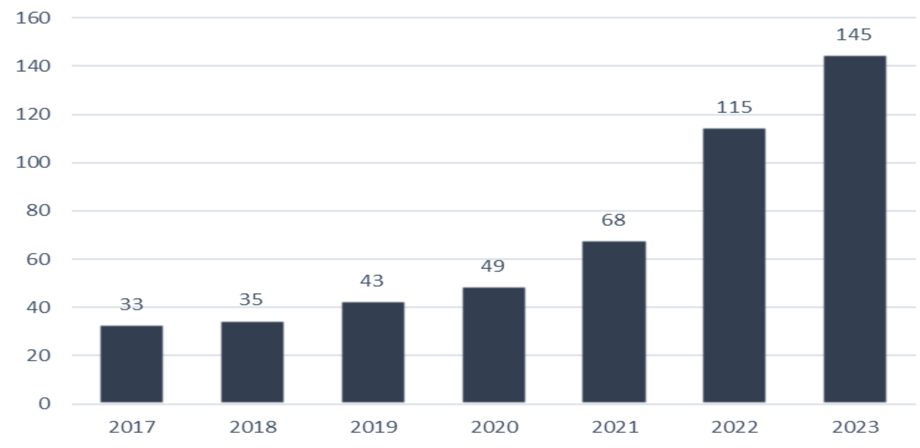
Following evaluation by the AOTMiT, the MoH forms an annual TLI list of rare disease and/or oncology therapies, and manufacturers of these therapies are free to choose whether to submit a reimbursement application under the TLI pathway. Only 14 of the 99 eligible therapies selected for evaluation in 2020-2024, which received marketing authorization in the EU during the respective horizon-scanning periods, have gained approval for reimbursement in Poland after fast-track TLI reimbursement procedures. Another 12 have gained reimbursement in Poland through standard reimbursement procedures. The number of therapies selected by the MoH for the final annual TLI lists – selection for which is required in order to be eligible to undergo a fast-track TLI procedure – has remained controversially low, except for 2022. The low number of therapies selected in 2024 is particularly noteworthy.

Number of therapies evaluated, listed and reimbursed under TLI system



The launch of the fast-track TLI reimbursement pathway in 2020 coincided with, and contributed to, an ongoing period of unprecedented growth in the number of new originator therapies (including new indications) gaining reimbursement in Poland. From a total of 49 in 2020, the number almost tripled to 145 in 2023.

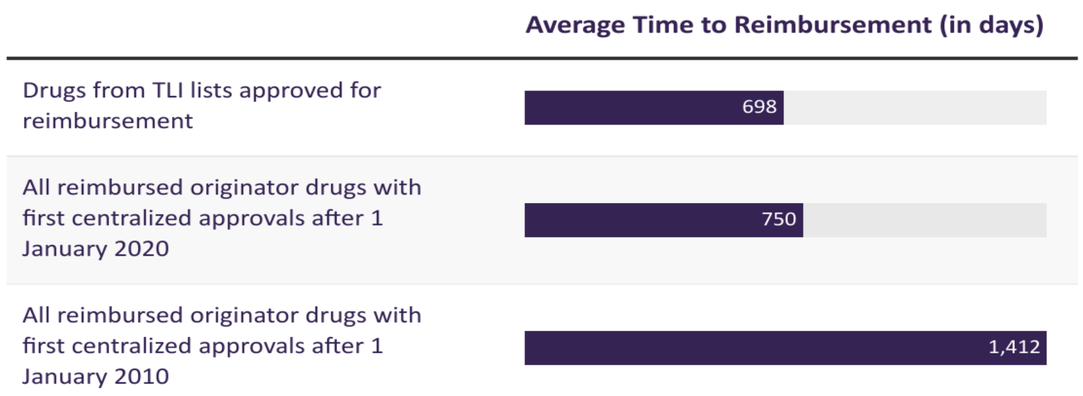
Number of new therapies/indications receiving positive reimbursement decisions, 2017-2023



Source: MoH

According to GlobalData’s POLI database, medicines approved for reimbursement after undergoing TLI procedures had a moderately shorter average time to reimbursement (698 days) than the average for all originator medicines obtaining their first centralized approval between 1 January 2020 and 1 October 2024 (750 days). This compares with an average time to reimbursement of 1,412 days for all originator medicines gaining their first centralized approval between 1 January 2010 and 1 October 2024.

Average time to reimbursement, TLI vs all on-patent medicines



*Note: parallel import and withdrawn products have been excluded from the analysis

Source: GlobalData

Conclusions

The introduction of the fast-track TLI reimbursement mechanism has had a moderately positive impact on access to new high-cost centrally-approved therapies in Poland. It has helped to bring advanced therapy medicinal products (ATMPs) Zolgensma (onasemnogene abeparvovec) and Tecartus (brexucabtagene autoleucel) to patients more quickly than would have otherwise been possible. However, it has not delivered the broad access to novel therapies that was anticipated when the Medical Fund Act was first presented. In part, this is thanks to the prevailing financial caution of Polish lawmakers and regulators, but it is also because of the reluctance of some manufacturers to engage with the new mechanism, due to certain punitive aspects – for example, the requirement to continue funding the therapy if the term of a TLI reimbursement decision ends and no new reimbursement decision follows. The addition of the TLI reimbursement pathway has coincided with a period of unprecedented growth in the number of new originator therapies gaining reimbursement in Poland, and with a marked improvement in the average time to reimbursement for new centrally approved medicines. It can be seen as an important element of the development of Poland’s pricing and reimbursement system, which is likely to be further modified and improved in the future.